

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: Bair Hugger Forced Air Warming
Devices Products Liability Litigation

MDL No. 15-2666 (JNE/FLN)

This Document Relates to All Actions

**PLAINTIFFS' MEMORANDUM IN
SUPPORT OF MOTION TO
EXCLUDE OR LIMIT THE
TESTIMONY OF DEFENDANTS'
EXPERT MICHAEL A. MONT, M.D.**

Michael A. Mont, M.D. is an orthopedic surgeon who is being offered as an expert by 3M Company and Arizant Healthcare, Inc. Plaintiffs do not dispute that Dr. Mont is a sufficiently qualified orthopedic surgeon who has a basis to testify about the nature of orthopedic surgeries, the use of the Bair Hugger in those surgeries, and issues of medical opinion that reasonably relate to his surgical expertise. Indeed, Plaintiffs agree with a great number of Dr. Mont's opinions, including:

1. The majority of periprosthetic joint infections are initiated through the introduction of microorganisms at the time of surgery. Ex. A¹, Mont Dep. at 319:10-14;
2. Strategies should be utilized to lower particulate and bacterial counts at the surgical site. *Id.* at 321:5-21;
3. That the probability of surgical site infection correlates directly with the quantity of bacteria that reach the surgical wound. *Id.* at 303:3-25;

¹ All references to Ex. __ are references to exhibits to the Declaration of Genevieve M. Zimmerman in Support of Plaintiffs' Motion to Exclude the Opinions and Testimony of Michael Mont, M.D., filed concurrently herewith.

4. Disruption of the unidirectional flow in an operating room can potentially cause the instruments, hands of the surgeon, and the implant to become contaminated. *Id.* at 321:5-21;
5. Fewer colony forming units are required to cause a periprosthetic joint infection than a superficial wound infection *Id.* at 324:5-8; and
6. Orthopedic surgeons would be concerned if a device was raising bioburden from underneath the operating room table and depositing it over the surgical site. *Id.* at 331:4-8; 337:10-15.

Ultimately, Plaintiffs do not challenge the admissibility of the overwhelming majority of Dr. Mont's opinions under *Daubert*. However, his report and testimony occasionally strayed beyond his field of expertise as an orthopedic surgeon. Some of the opinions offered by Dr. Mont relate to the effect of heat and air produced by other equipment and devices on the operating room environment. However, Dr. Mont has no expertise or education in biomedical engineering, fluid dynamics, heat transfer, or operating room ventilation. During his deposition testimony, Dr. Mont demonstrated a lack of qualifications, methodology, or scientific support to give meaningful opinions in these areas. As such, Plaintiffs ask the Court to limit Dr. Mont to his field of orthopedic surgery and exclude the opinions set forth below.

BACKGROUND

Fundamentally, the claims plaintiffs have asserted in this MDL boil down to two central scientific questions: (1) does the presence of particles in the air correlate with bacterial load, also known as bioburden; and (2) does the Bair Hugger system increase the number of particles in the operating room and over the surgical site during an

operation? The answer to the second question is uncontroverted: 3M's corporate representative Al Van Duren admitted that “[b]ased on the data that we have today, including the study funded by 3M as well as other studies, every single study indicates that the Bair Hugger increases the particle count over the sterile field.” Ex. B, Van Duren Dep. at 254:5. Dr. Michelle Hulse-Stevens, the company's Medical Director, likewise noted in internal documents that the medical consensus includes “almost uniform comment that FAW [forced-air warming] increase particulates in air.” Ex. C, 3M internal email - 3MBH00580475.

Thus, the central scientific question to be considered by the jury is whether or not these particles correlate with bacterial threat. This issue has been examined by a multitude of peer-reviewed studies which have concluded particle counts are a reliable method of determining the bioburden in the air, and that increased bioburden correlates with the incidence of periprosthetic joint infections. None of these publications have any conflicts of interest and were not funded, supported by, or associated with any person or entity with any type of interest in this litigation. These studies include:

- Darouiche, et al. “Association of Airborne Microorganisms in the Operating Room With Implant Infections: A Randomized Controlled Trial.” *Infection Control & Hospital Epidemiology* (2017). Ex. D
- Zheng et al. “Concentrations and Size Distributions of Airborne Particulate Matter and Bacteria in an Experimental Aviary Laying-Hen Chamber.” *Journal of the American Society of Agricultural and Biological Engineers* (2013). Ex. E
- Raval et al. “Real-time monitoring of non-viable airborne particles correlates with airborne colonies and represents an

acceptable surrogate for daily assessment of cell-processing cleanroom performance.” *Cyotherapy* (2012). Ex. F

- Stocks, et al. “Predicting bacterial populations based on airborne particulates: A study performed in nonlaminar flow operating rooms during joint arthroplasty surgery.” *American Journal of Infection Control* (2010). Ex. G
- Seal et al. “Electronic Particle Counting for Evaluating the Quality of Air in Operating-Theaters.” *Journal of Applied Bacteriology* (1990). Ex. H

Various experts proffered by both Plaintiffs and Defendants also agree with these studies. Likewise, the *International Consensus on Periprosthetic Joint Infection*² endorsed the conclusions found in this body of literature, with a “strong consensus” of 93% of the Delegates voting that “bacteria can be considered as part of the total mass of particulates in the air.”

Unable to ignore the fact that the Bair Hugger increases particles over the surgical site by disrupting the protective effect of operating theater ventilation, and lacking the ability to dispute that these particles represent biological threats, Dr. Mont instead speculates that other objects and activities in the operating room could create more substantial disruptions. In doing so, Dr. Mont ultimately claims that nearly every object in the operating room *except* the Bair Hugger is a possible source of airborne contamination. It is this unqualified speculation that Plaintiffs seek to address with their Motion.

² Ex. I, *Operative Environment*, 2014 Orthopaedic Research Society, J. ORTHOP. RES. 32:S60-S80 (2014). Dr. Mont considers this publication very authoritative. Ex. A (Mont Dep at 233:4-9)

LEGAL STANDARD

While the United States Supreme Court favors admission of expert testimony under Rule 702, there are limits to what expert witnesses can be permitted to share with the jury. Federal Rule of Evidence 702 permits expert witnesses to testify only if the witnesses are qualified to express their opinions and the proposed evidence upon which they base their testimony is reliable or trustworthy. *Polski v. Quigley Corp.*, 538 F.3d 836, 839 (8th Cir. 2008). The party seeking admission of expert testimony has the burden of demonstrating its reliability. *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1042 (D. Minn. 2007).

“If the proffered expert testimony is not based on independent research, the party proffering it must come forward with other objective, verifiable evidence and explain precisely how they went about reaching their conclusions and point to some objective source—a learned treatise, the policy statement of a professional association, a published article in a reputable scientific journal or the like—to show that they have followed the scientific method, as it is practiced by (at least) a recognized minority of scientists in their field.” *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317-19 (9th Cir. 1995) (*Daubert II*). The court should not admit opinion evidence “that is connected to existing data only by the *ipse dixit* of the expert.” *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 157 (1997). Here, Dr. Mont’s testimony fails to show any methodology or foundation that would meet the standards of *Daubert* when opining about the dynamics of other equipment in the operating room and the potential effect on theater ventilation.

ARGUMENT

Plaintiffs seek to exclude three of Dr. Mont's opinions. First, Dr. Mont's opinion regarding the potential airflow impact of other items in the operating room is based on pure speculation and strays far beyond his expertise in orthopedic surgeries. Second, Dr. Mont's opinion that there are other sources of heat disruption in the operating room more significant than the Bair Hugger has no support apart from his own *ipse dixit*. Finally, Dr. Mont intends to offer the opinion that the Bair Hugger device is not even a "possible" source of contamination in an operating room, even while maintaining that almost everything else in the room *is* a "possible" source of contamination. Dr. Mont lacks the qualifications and evidentiary support to arrive at these conclusions in a reliable manner.

I. Dr. Mont Lacks the Qualifications and Evidentiary Support to Opine that that Other "Things" in the Operating Room Impact Protective Ventilation.

In his report, Dr. Mont opined that "[m]any things in the operating room impact airflow." Ex. J (Mont Rpt. at 10-11.). However, Dr. Mont's is not an engineer, has never taken a class in fluid dynamics, has never taken a class on heat transfer, and provided no basis for his opinions with respect to the effect on the downward air flow by moving objects except that he read some articles. Ex. A (Mont Dep. at 247:18-20; 248:5-6; 248:7-8; 248:1-249:2). In fact, Dr. Mont could not offer any scientific basis for his opinion that any of the "many things in an operating room impact air flow" and no scientific basis or even evidence that the "many things" can cause a periprosthetic joint infection. *See, e.g., id.* at 251:23 – 252:2.

Dr. Mont stated in his report:

[i]t was claimed by Plaintiffs' experts that the Bair Hugger can impact airflow in the operating room. In my opinion, even if this was the case, it would be infinitesimal in comparison to so many other sources of airflow generation in the operating room, which include:

1. Surgeon traffic
2. Surgical assistants
3. Nurse or Surgical techs.
4. Circulating nurses.
5. Other members of operating room team.
6. Doors opening and shutting creating wind currents.
7. Moving of lights and other equipment directly creates waves or currents by individual (surgeon or team), as well as the specific object moving.
8. Many pieces of equipment in the OR generate air currents, including those that have cooling fans.

Ex. J (Mont Rpt. at 9).

However, Dr. Mont provided no scientific basis or methodology for his opinion. For example, with respect to items 1 through 5, pertaining to the personnel in the operating room, Dr. Mont has no knowledge of the volume of air flow produced by the movement of people in an operating room. Ex. A (Mont Dep. at 261:4-8). Even if he knew, Dr. Mont cannot offer the opinion if the amount of airflow would disrupt the downward unidirectional airflow because he does not know what volume of flow is required to disrupt the protective effect of the airflow in an operating room. *Id.* at

262:24-263:7. Like many of his opinions, Dr. Mont holds the opinion that as long as he recalls reading it somewhere, he can opine on it in a court of law. *Id.* at 248:11-24.

Further, with respect to item number 7, “Moving of lights and other equipment directly creates waves or currents by individual (surgeon or team), as well as the specific object moving,” Dr. Mont does not know the volumetric airflow from moving lights. *Id.* at 263:8-13. And again, Dr. Mont has no knowledge or reliable scientific basis that “Many pieces of equipment in the OR generate air currents, including those that have cooling fans” as identified in item 8 above have any effect on airflow in the room. *Id.* at 251:9-11. In fact, Dr. Mont admits that there is no evidence that a cooling fan of an anesthesia machine has ever caused a periprosthetic joint infection. *Id.* at 251:23-252:2.

Dr. Mont is not a biomedical engineer, and he is not an expert in ventilation. *Id.* at 242:8-11. Dr. Mont does not have the expertise to offer any opinions regarding the potential effect of other devices and activities on operating room ventilation, and his testimony on those issues should be excluded.

II. Dr. Mont Lacks the Qualifications and Evidentiary Basis to Opine that there are Sources of Heat in the Operating Room that Exceed the Heat Generated from the Bair Hugger Device.

In his report, Dr. Mont stated that “[t]here are many sources of heat generation in the operating room that are far in excess of any heat generated from the Bair Hugger device.” Ex. J (Mont Rpt. at 10). However, Dr. Mont does not have any knowledge of the amount of heat these “many sources” produce. Dr. Mont identifies many sources of heat in the operating room of lower extremity joint arthroplasties, including:

1. Saw blades on bone - with the bone generating heat.

2. Batteries that power the saw blades as they are used.
3. Many surgeons use hooded gowns with battery packs (space suits), and air is blown inside these suits.
4. General overhead lights in any operating room.
5. Focused overhead lights directly at field (usually 2 of them).
6. Ancillary hooded lights that many surgeons wear (and the light generating unit).
7. All personnel in operating room.
8. Machine to process fluid irrigation fluids.
9. Often other power sources for special blades used in some surgeries (more often revisions) for burring bone, cement, *etc.*
10. Standard electrocautery devices.
11. Ancillary cautery devices - Plasmablade, Aquamantis, Canady, and others.
12. Various ancillary devices in the operating room by anesthesiologist, *e.g.* defibrillator, computer, their monitor, *etc*; their anesthesia machine is a source of heat.

Id. at 10-11.

Similar to the “other things” that disrupt airflow, Dr. Mont has no knowledge of the amount of heat produced by items 1 through 12. Ex. A (Mont Dep. at 271:2 - 280:11). With respect to high temperature surgical tools, Dr. Mont could not say “whether or not that quick burst of heat affects the unidirectional flow in an operating room.” *Id.* at 277:19-22. In fact, Dr. Mont has never studied the effect of heat on unidirectional flow

in an operating room. *Id.* at 281:1-5. Furthermore, most if not all the sources of heat that Dr. Mont outlines that produce heat are all above the surgical table and are not producing heat below the operating room table. *Id.* at 271:2 - 280:11. Dr. Mont's confusion arises because of his lack of expertise in the areas of airflow engineering and thermodynamics, and perhaps his failure to fully grasp Plaintiffs' claims in this case, *i.e.*, that the heat generated by the Bair Hugger causes convective currents which carry bacteria above the surgical table and increase the bioburden at the surgical site.

Finally, Dr. Mont's opinion that "the Forced Air Warmer, which is away from the operative field, and has a negligible effect compared to many of the devices or other sources of heat generation mentioned above" is not based on any stated methodology or scientific evidence. Indeed, Dr. Mont has absolutely no knowledge or understanding of the Bair Hugger device at issue. Dr. Mont does not know the volumetric flow of air coming from the Bair Hugger. *Id.* at 263:18-21. Nor does Dr. Mont know the amount of heat the Bair Hugger produces. *Id.* at 263:22-264:4. His concession that he does not know the amount of heat or air produced by the Bair Hugger in and of itself indicates that his opinion comparing the Bair Hugger to other sources of heat is unreliable and thus not helpful to the jury.

III. Dr. Mont's Opinion that Patient Warming Devices are not Potential Sources of Contamination in the Operating Room Should be Excluded as Unreliable

Both in his report and during his deposition,, Dr. Mont testified there are numerous sources of contamination in the operating room, including the skin of the patient, movement and air flow in the operating room and a number of devices found in

the room, such as suction tips, blades, saws, light handles, etc. *See, e.g., id.* at 105-106. However, when asked whether he would agree with the proposition that “patient warming devices are potential external sources of contamination in the operating room,” Dr. Mont answered, “No, I don’t agree with that.” *Id.* at 108. This answer strains credibility and indicates a clear intent on the part of Dr. Mont to specifically refuse to admit even an obvious fact that might be contrary to his pre-conceived notions of how his testimony should be framed in order to benefit the Defendants.

Dr. Mont intends to testify—without any scientific evidence or methodology to support his claims—that practically everything in the operating room is a potential source of infection *except the device he is being paid to exclude as a source of such infections.* Of course, neither in his report nor in his deposition did Dr. Mont identify any evidence whatsoever that the items he believes are other “potential sources of infection” actually have the capability to increase infection risk in the operating room. Thus, it is a very convenient—but scientifically baseless—opinion offered by Dr. Mont that the only device in the operating room that does not contribute to increased infection risk happens to be the device that is the subject of this litigation. This convenient opinion concerning other operating room devices that supposedly create more risk than the Bair Hugger should be viewed as exactly what it is—pure speculation—and excluded from consideration by the jury.

IV. Dr. Mont Intends to Offer Testimony on Subjects in which he does not have the Requisite Expertise.

Dr. Mont's field of expertise is purely as an orthopedic surgeon. He acknowledges that he is not an engineer, nor is he an expert in infectious disease or microbiology. *Id.* at 122:23; 219:5-17. However, careful exercise of this Court's gatekeeping function is necessary because Dr. Mont has expressed his willingness to depart from his field when offering his commentary, stating "I'm allowed to have an opinion about many topics that are outside my expertise." *Id.* at 250:6.

For example, Dr. Mont admits that he is not an expert in the design of an operating room, and would "defer to others" in regard to such designs, yet he intends to testify as to the potential sources of infection and how they might or might not be affected by the design of an operating room. *Id.* at 202. It is worth noting again that Dr. Mont admits he is not an expert on either the Bair Hugger device or other devices designed to prevent hypothermia, yet he intends to testify that normothermia serves to prevent infections during surgery. *Id.* at 239. Dr. Mont admitted in deposition that no medical study in fact has ever shown that avoidance of hypothermia actually decreases infection risk in orthopedic implant cases, but instead he simply "believes" that prevention of infections through the use of patient warming devices has been established or is just common knowledge or accepted. *Id.* at 235. In short, he summarily concludes that forced air warming decreases infection risk, without any specific or scientific basis for this assertion, while acknowledging there is no published study that supports this conclusion. These are precisely the kinds of conclusory and speculative opinions that should be excluded from the jury as unreliable under *Daubert*.

Dr. Mont admits that he is not an expert in either ventilation or laminar flow, yet he intends to testify that the placement of a Bair Hugger device within two feet of a patient during surgery would in no way affect whether the airflow from the device might increase the chance of infection in a patient. *Id.* at 188; 242-244. Dr. Mont is unqualified to offer this opinion. Additionally, while Dr. Mont stated in his expert report that the Bair Hugger device is kept well away from the patient, by the time of his deposition, he testified that even placing the device within two feet of the patient would have no adverse effect on operating room ventilation. *Id.* at 188.

CONCLUSION

Given Dr. Mont's attempt to speculate on matters outside his personal knowledge and relevant field of expertise as an "expert", this Court should carefully limit him to medical opinions and analysis reasonably connected to his training and experience in orthopedic surgery. Dr. Mont lacks the qualifications and the evidentiary basis to offer opinions relating to the effect of heat and air produced by other equipment and devices on the operating room environment, nor can he reliably provide opinions in the field of biomedical engineering and microbiology. As such, this Court should exclude such opinions and confine Dr. Mont to matters relating to his field of expertise.

Respectfully submitted,

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